

SM



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,846	08/31/2000	Timothy Hla	UCT-0012	4421
23413	7590	03/31/2004	EXAMINER	
CANTOR COLBURN, LLP			EPPS FORD, JANET L	
55 GRIFFIN ROAD SOUTH			ART UNIT	
BLOOMFIELD, CT 06002			PAPER NUMBER	

1635

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84

**Advisory Action**

Application No.

09/651,846

Applicant(s)

HLA ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE ATTACHED.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: \_\_\_\_\_

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

*Janet L. Epps-Ford*  
 Janet L. Epps-Ford  
 Patent Examiner  
 Art Unit 1635

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejection of claims 35, 56, and 74-75 under 35 USC 112, 1st paragraph.

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 33-82 are pending. Claims 33-40, 54-61 and 73-78 are currently under examination. Claims 41-53, 62-72 and 79-82 are withdrawn as being drawn to non-elected subject matter as set forth in the Paper filed 5-10-2002.

### ***Response to Arguments***

3. The rejection of claims 35, 56, and 74-75 is withdrawn in response to Applicant's arguments filed 2-19-04. However, claims 35, 56, and 74-75 are not allowable since they depend from a rejected base claim.
4. Claims 33-34, 36-40, 54-55, 57-61 and 73, and 76-78 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons of record as set forth in the prior Office Action mailed 5-06-03.

Applicant's arguments filed 2-19-04, have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Applicants have reduced to practice two antisense oligonucleotides to human EDG-1 (SEQ ID NOs. 1 and 2) and one antisense oligonucleotide to EDG-3 (SEQ ID NO: 5), wherein these antisense oligonucleotides include the translation initiation site. Moreover, Applicants make reference to the definition of oligonucleotide as defined by the NIH Medical Subject Headings as a polymer made up of a few (2-20) nucleotides. Therefore, Applicants argue that given the definition of

oligonucleotide and the requirement that the oligonucleotide include the translation initiation codon, one of ordinary skill in the art could readily design an oligonucleotide that meets these criteria based on the nucleotide sequences for human EDG-1 and EDG-3, which have been entered by sequence amendment. Contrary to Applicant's assertions, the definition that Applicants cite for the term "oligonucleotide" was not found in the specification as originally filed, therefore it is inappropriate for Applicants to require the examiner to limit the term "oligonucleotide" set forth in the claims to the definition set forth in the NIH Medical Subject Headings.

As stated in the prior Office Action, written description requires that Applicants be in possession of the full scope of the claimed invention as of the filing date of the patent application. Applicants suggests that with the knowledge of the EDG-1 and EDG-3 sequences one could readily make antisense targeting these sequences, however it is apparent that Applicant is suggesting that further experimentation be performed in order to isolate the claimed invention. As argued previously, there is a high level of unpredictability in the antisense art for design of functional antisense absent the sequence structure of the target sequence and knowledge of suitable regions that are open to binding by a particular antisense sequence. The claims are broadly drawn to antisense oligonucleotides that inhibit the expression of nucleic acid encoding human EDG-1, or EDG-3 receptors. The instant claims are not limited to the human EDG-1 receptor or EDG-3 receptor nucleic acid sequence as recently submitted by Applicants. Additionally, the instant claims do not recite any particular length in regards to the claimed antisense oligonucleotides. Other than the antisense oligonucleotide sequences according to SEQ ID NO: 1, 2, and 5, Applicant has not provided any other structural information that would allow

one of skill in the art to predict the structures of all antisense oligonucleotides encompassed by the instant claims. Therefore the instant claims encompass a genus of antisense oligonucleotides targeting all polymorphic, allelic, and splice variants of nucleotide sequences encoding human EDG-1 or EDG-3 receptors.

Therefore, a mere wish or plan to identify antisense oligonucleotides that function to bind and inhibit expression of EDG-1 or EDG-3 is not sufficient to establish that Applicant's invention was sufficiently reduced to practice such that Applicants had full possession of the claimed invention at the time of filing of the instant invention.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford, Ph.D.